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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,930	03/22/2001	Ellen Heber-Katz	00486.00006	1820
22907	7590	04/27/2004	EXAMINER	
BANNER & WITCOFF 1001 G STREET N W SUITE 1100 WASHINGTON, DC 20001			LACOURCIERE, KAREN A	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 04/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 15-19, 24, 25 and 27-30 is/are pending in the application.
- 4a) Of the above claim(s) 3-5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 16, 18 and 24 is/are rejected.
- 7) ☒ Claim(s) 2, 15, 17, 19, 25 and 27-30 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413)

## **DETAILED ACTION**

### ***Election/Restriction***

Claims 3-5 are maintained as withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

### ***Claim Rejections - 35 USC § 112***

The rejection of record of claim 22 under 35 U.S.C. 112, second paragraph, is withdrawn in response to Applicant's amendments filed 02-05-2004.

### ***Claim Rejections - 35 USC § 102***

The rejection of record of claims 1, 2, 16-19, 21 and 22 under 35 U.S.C. 102(b) as being anticipated by Treadwell et al. is withdrawn in response to Applicant's amendments filed 02-05-2004.

The rejection of record of claims 1, 2, 16-19, 21, and 23-26 under 35 U.S.C. 102(b) as being anticipated by Corte, et al. is withdrawn in response to Applicant's amendments filed 02-05-2004.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 16, 18 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenbaum et al.

Rosenbaum et al. disclose treating euthyroid patients with congestive heart failure with the drug amiodarone. 1-2% of those patients developed hypothyroidism (see for example Table IV) and, therefore, had a decreased level of a thyroid hormone relative to a euthyroid adult to whom the drug has not been administered. Amiodarone causes a decrease in T3 levels, as evidenced by, for example, Ahmed et al. (see for example, comment, page 828). Rosenbaum et al. do not explicitly state that the healing of ischemic damage resulted from the lowered thyroid level, however, this increased healing is expected to be inherent, as the method produces the same thyroid hormone lowering as the claimed methods and, therefore, would be expected to have the same outcome.

Claims 1, 16, 18 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Ahmed et al.

Ahmed et al. disclose administering amiodarone and lithium to a euthyroid adult with ischemic heart disease, producing a decrease in thyroid hormone levels, including T3 levels (see for example, comment on page 828), relative to a euthyroid adult to whom the drugs have not been administered. Ahmed et al. do not explicitly state that the healing of ischemic damage resulted from the lowered thyroid level, however, this

hormone lowering as the claimed methods and, therefore, would be expected to have the same outcome.

### ***Claim Objections***

The objection to claim 21, set forth in the prior Office action, is withdrawn in response to Applicant's amendments filed 02-05-2004.

Claims 2, 15, 17, 19, 25 and 27-30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (571) 272-0759. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Lacourciere  
April 15, 2004

  
KAREN A. LACOURCIERE, PH.D  
PRIMARY EXAMINER